UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,327	05/25/2000	Neil H. Riordan	RIORD.004A	7262

20995 7590 05/02/2003

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	21

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/579,327	Riordan et al
Examiner	**Art Unit**
Mark Navarro	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Apr 25, 2003* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: _____

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ .

10. ☐ Other:

ADVISORY ACTION

Applicants response filed April 25, 2003 (Paper Number 19) has been received and entered. Consequently, claims 1-21 and 34-39 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-21 and 34-39 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "substantially free of added raffinose and added enzymes." is maintained.

Applicants are asserting that the term "substantially" as used in claims 1 and 16 of the present invention, is a definite term. Furthermore, Applicants assert that "substantially free" is found in many granted patents, and thus the rejection of the terms "substantially free" in the claims should be withdrawn. Applicant's further assert that examples of "substantial" amounts of raffinose can be found in the cited prior art, for example Pancholi et al (6,190,659) use 30% raffinose. Applicant's contend that this is a "substantial amount."

Applicant's arguments have been fully considered but are not found to be fully persuasive.

First, Applicant's cited case law deals with the term "substantially" as opposed to the instant application which recites "substantially free." "Substantially exclusive lacks definitiveness." *Quaker Oil Corp. v. Quaker State Oil Refining Corp.* (PO TM TappBd) 161 USPQ 547.

Second, Applicants assert that "substantially free" is found in many granted patents, and thus the rejection of the terms "substantially free" in the claims should be withdrawn. However, each application is examined on its own merits. While one application may provide a definition of the term, "substantially free" another application may not, or provide a different definition. Consequently, the use of the term itself is not an indication of whether or not the metes and bounds of the term can be determined.

Finally, Applicants assert that Pancholi et al use 30% raffinose, and that one of ordinary skill in the art would consider this a "substantial amount." However, this still does not address the line of demarcation. At what point is an amount no longer substantially free? Without clear guidance as to where this point is, one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

For reasons of record in Paper Number 17, as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 1-21 and 34-39 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. This is a new matter rejection.

Applicant's are asserting that support for the limitation "substantially free of raffinose" can be found throughout the specification, since there is no teaching or suggestion that raffinose is added to the acid treatment solution, anywhere in the specification.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be fully persuasive in view of the term "substantially free." If as Applicants assert "there is no teaching or suggestion that raffinose is added to the acid treatment" how can the claim now encompass a finite, but undetermined amount? While there would appear to be support for "not adding raffinose" this is not commensurate in scope with the instantly filed claims which recite "substantially free of added raffinose."

For reasons of record in Paper Number 17, as well as the reasons set forth above, this rejection is maintained.

3. The rejection of claims 1-21 and 34-39 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. This is a new matter rejection.

Applicants are asserting that upon reading the specification, one of skill in the art would clearly understand that an "acid treatment solution" can have a full range of pH possibilities that would be effective to create an immune-stimulating composition. Applicants assert that one of skill in the art would know that an "acid treatment solution" could easily have a pH of, for example, 6.0 or 5.0 or 4.0, etc.

Applicant's arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that upon reading the specification, one of skill in the art would clearly understand that an "acid treatment solution" can have a full range of pH possibilities that would be effective to create an immune-stimulating composition. However, this again begs the question, why pick less than a pH of 6.8? Could the fact that art was applied using a pH of exactly 6.8 have had any influence upon picking this magical number? Clearly without specific support within the specification, a pH of less than 6.8 is considered new matter.

Applicants further assert that one of skill in the art would know that an "acid treatment solution" could easily have a pH of, for example, 6.0 or 5.0 or 4.0, etc. However, Applicants are again trying to narrow the range from a broadly disclosed acid (pH 0-6.99999) to one with a range of only 0-6.799999. Without specific support for such a limitation, this again is considered new matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

April 30, 2003